

**Notice of Allowability**

Application No.

09/673,448

Applicant(s)

CLARK ET AL.

Examiner

Jeanine A. Goldberg

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/20/05; 11/7/05.
2. ☒ The allowed claim(s) is/are 110-142.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 8/04
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
- ☐ Examiner's Amendment/Comment
- ☒ Examiner's Statement of Reasons for Allowance
- ☐ Other \_\_\_\_\_

*J. Goldberg*  
JEANINE A. GOLDBERG  
PRIMARY EXAMINER

1/2/06

### **DETAILED ACTION**

1. This action is in response to the papers filed October 20, 2005 and November 7, 2005. Currently, claims 110-142 are pending. All arguments have been thoroughly reviewed.

### **REASONS FOR ALLOWANCE**

2. The following is an examiner's statement of reasons for allowance.

The claims have been amended to be directly to detecting prostate and liver cancer by detecting methylation in the intragenic (non-promoter) of the GST Pi gene.

With respect to the addition of SEQ ID NO: 60 into the claims, while New rule 37 CFR 1.57 (b) does not apply to the instant application because it was filed prior to October of 2004, the rule does make clear that the purpose was to codify the practice of the office. Thus, the rule is pertinent to the extent it is a codification of practice prior to October 2004. With respect to the addition of SEQ ID NO: 60 into the claims, upon review of the specification and the arguments, the specification illustrates substantial portions of the GST-Pi gene sequence of Genbank Accession No. M24485 in Figure 1. The original claims was also directed to GST-Pi gene and the specification indicates the numbering is relative to Genbank Accession Number M24485. Thus, incorporation of SEQ ID NO: 60 which is Genbank Accession Number M24485 is not new matter.

Moreover, Lee does not discuss methylation changes in the intragenic portion of GSTP1. The nested primers of primer set A and B of Lee is directed to the promoter

region. Thus, claims directed to the intragenic region of the GSTPi gene are not suggested or taught by Lee.

Thus, the claims are novel and unobvious in view of the prior art.

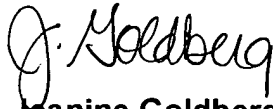
3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272- 0745.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

  
**Jeanine Goldberg**  
**Primary Examiner**  
January 3, 2006